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CURTIS F. RIBANDO
USDA-ARS-OC1
NATIONAL CENTER FOR AGRICULTURAL
UTILIZATION RES. 1815 N. UNIVERSITY ST.,
PEORIA, IL 61604

W11P2,3 EXAMINER

ART UNIT PAPER NUMBER
168 13

DATE MAILED: 09/06/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

Relin D+E+Decl.

This application has been examined Responsive to communication filed on 4/26/91 5/30/91 6/10/91 This action is made final.
A shortened statutory period for response to this action is set to expire 3 month(s), 10 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
 2. Notice re Patent Drawing, PTO-948.
 3. Notice of Art Cited by Applicant, PTO-1449.
 4. Notice of Informal Patent Application, Form PTO-152.
 5. Information on How to Effect Drawing Changes, PTO-1474.
 6. _____

Part II SUMMARY OF ACTION

1. Claims 9-34 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
 2. Claims 1-8 have been cancelled.
 3. Claims _____ are allowed.
 4. Claims 9-34 are rejected.
 5. Claims _____ are objected to.
 6. Claims _____ are subject to restriction or election requirement.
 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
 8. Formal drawings are required in response to this Office action.
 9. The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
 10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner; disapproved by the examiner (see explanation).
 11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).
 12. Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____
 13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
 14. Other

Claims 9-34 are rejected under 35 U.S.C. 103 as being unpatentable over Johnson et al. (Gamete Research 17:203-212 (1987), Johnson et al. (Gamete Research 16:1-9 (1987) and Johnson et al. (Gamete Research 21:335-343) all in view of GB 2,145,112 and Handbook of Histopathological and Histochemical Techniques.

The primary references all disclose methods of sorting sperm. First, all of these references disclose staining sperm collected from a male mammal with a fluorescent stain capable of selectively staining DNA in living cells (specifically Hoechst 33342). The claims require a dyeing temperature of 30-39°C for a period of time sufficiently long for staining to take place uniformly but sufficiently short to preserve viability of the sperm. None of the Johnson references disclose the staining temperature and suggest a staining time of at least 30 minutes. GB'12 describes staining the sperm for 2 hours at room temperature. Handbook of Histopathological and Histochemical Techniques, at page 192, states that "[a] reduction in staining time of certain procedures may usually be effected by the application of heat." Even though this reference is drawn particularly to histological staining techniques, it appears that the incubation of sperm at temperatures of 30-39 °C in order to reduce staining time is, in absence of objective evidence to the contrary, well within the skill of the practitioner such that it would be expected that an increase in temperature during staining of sperm would result in a decreased staining time. As sperm exists physiologically in the testis at temperatures around 35°C and in the vagina at temperatures around 37-38°C and in expectation of the fact that sperm are very short-lived cells, it would have been obvious to incubate sperm at temperatures at which sperm exists physiologically in order to minimize holding time prior to separation and insemination. Further, there is no showing of unexpected result as the percent efficiency of sperm sorting of the Johnson references is within that claimed. Second, the means used to sort sperm in the Johnson references is the modified EPICS V flow cytometer/cell sorter which is the

same as that used by applicant. The modifications include the presence of a means to properly orient sperm within the flow of sheath fluid, two detecting means and a gating means to eliminate improperly oriented sperm. Finally, the use of phosphate buffered saline with 0.1% albumin as the sheath fluid and modified egg yolk extender as the collecting fluid is considered to be conventional in the art.

The declaration under 37 CFR 1.132 filed May 30, 1991 is insufficient to overcome the rejection of claims 9-34 based upon 35 USC 103 as set forth in the present Office action because, in view of the teaching of Handbook of Histopathological and Histochemical Techniques, the results shown in the declaration are not unexpected.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 188.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jean C. Witz whose telephone number is (703) 308-3073. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


8/30/91


DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
ART UNIT 188